



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g 3400d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

July 2, 2002

WARNING LETTER

NWE-21-02W

VIA FEDEX

Ronald J. Cataldo, Owner
William's Candy Company, Inc.
18 Main Street, Winter Hill
Somerville, Massachusetts 02145

Dear Mr. Cataldo:

The Food and Drug Administration (FDA) conducted an inspection of your facility located at 18 Main Street, Somerville, Massachusetts, on February 5, 6, 8, 21 and March 1, 2002. Based on our review of product labels collected during the inspection, we have determined that your Pistachio Cream, Maple Walnut, Swiss Fudge, Peanut Butter Chips, and Peanut Butter Melts are misbranded within the meaning of section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act) as follows:

- The products Pistachio Cream, Maple Walnut, and Swiss Fudge are fabricated from two or more ingredients, but the labels fail to bear the common or usual name of each ingredient in the product, as required by section 403(i)(2) of the Act and by Title 21 of the Code of Federal Regulations section 101.4(a)(1) [21 CFR 101.4(a)(1)]. Specifically, the labels for your Pistachio Cream and Maple Walnut candies list the ingredient convertit and your Swiss Fudge label lists the ingredient white couverture. These do not appear to be the common or usual names for these ingredients.

- Your products Peanut Butter Chips and Peanut Butter Melts list the standardized foods peanut butter and chocolate in the ingredient listing. Furthermore, the standardized food milk chocolate is identified in the ingredient lists for Swiss Fudge, and Butter Crunch. However, the ingredient statements for these products fail to bear the common or usual name of each ingredient in the standardized foods, as required by 21 CFR 101.4(b)(2). This requirement may be met either by parenthetically listing the component ingredients contained in each of the standardized foods after the name of the standardized food, or by listing the component ingredients without listing the standardized food itself. Under the first alternative, the component ingredients must be listed in descending order of predominance in the standardized food; under the second, the component ingredients must be listed in descending order of predominance in the finished food.

The above violations are not meant to be an all-inclusive list of deficiencies in your labeling or at your facility. You should take prompt action to correct these violations, to establish procedures whereby such violations do not recur, and to review your operations and your product labels to ensure compliance with all applicable laws and regulations. Ensuring compliance with the laws and regulations is your responsibility. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction. Information related to FDA laws and regulations, including the act and 21 CFR, may be obtained through links at www.fda.gov.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you have taken to correct the violations. For corrections that you cannot complete within the fifteen (15) working days, state the justification for the delay and your timeframe for completion. Please provide documentation of the corrections as they are made, including copies of any revised labels, and explain your plan for preventing such violations in the future.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180.

Sincerely,



Gail T. Costello
District Director
New England District Office